REMARKS

Claims 1-9 and 11-15 are pending in the application. Reconsideration is respectfully requested in view of the above changes and the following remarks.

Claims 1 and 10 have been combined and Claim 10 is cancelled. Claims 2 to 4 as amended relate to the prosthetic graft of Claim 1.

Claim 5 has been amended to specify that a polymer is formed through cross-linking dextran and that the polymer comprises bonds sufficiently labile to permit resorption at an appropriate rate for tissue ingrowth upon implantation of the graft into a human or animal body. There is basis for this amendment at page 4, lines 1 to 7 of the Application as filed.

A minor typographical error has been corrected in Claim 9 as amended which refers to plasticising said cross-linked dextran, rather than practising said cross-linked dextran. There is basis for this amendment at page 7, lines 11 to 14 of the specification as filed.

Claim 11 has been amended to recite a method of forming a prosthetic graft impregnated or coated with a bioresorbable sealant composition comprising polymerised dextran. There is basis for this amendment at page 6, lines 6 to 16 of the Application as filed.

Claim 13 has been amended to correct a minor typographical error.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph as

being indefinite. This claim has been amended to refer to dextran, and there is antecedence for this term in Claim 1.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Malhotra et al. (US 5,212,008). Reference is made to Bustard et al. (US 4,230,597) to evidence an implicit feature of Malhotra et al.

Malhotra et al. discloses coated recording sheets for use in copying and printing applications (see column 1, lines 5 to 8). In contrast, Claim 1 as amended relates to a prosthetic graft. There is no disclosure in Malhotra et al. that the recording sheets disclosed therein would be suitable for use in any surgical procedure, and the recording sheets disclosed in Malhotra et al. are not suggested as being suitable as prosthetic grafts, and additionally are non-sterile.

Claim 1 and dependent Claim 2 as amended are thus novel and inventive over the disclosure made in Malhotra et al.

Claims 11 to 14 are rejected under 35 U.S.C. 103(a) as being obvious over Malhotra et al. in view of Bustard et al.

Malhotra et al. discloses coated recording sheets for use in copying and printing applications, and a method of forming such sheets. Malhotra et al. does not teach any method of forming prosthetic grafts. The disclosure of Malhotra et al. is concerned with a totally disparate field to the invention as now claimed and one of ordinary skill in the art would not consider using ink jet technology in the field, of prosthetic grafts. As noted above, Malhotra et al. does not make any suggestion that the recording sheets disclosed therein would find utility in any surgical field

particularly not the field of prosthetic grafts. Neither Malhotra et al. nor Bustard et al. suggest the step of introducing a flexible graft material into a mixture of dextran, formaldehyde and urea and then causing polymerization to occur within or on the graft *in situ* to produce a graft impregnated with or coated with the bioresorbable sealant as formed. Furthermore, one of ordinary skill in the art would have no motivation to combine Malhotra et al. (relating to ink jet technology) and Bustard et al. (relating to radioactive waste materials).

Applicants submit that Claims 11 to 14 as amended are novel and inventive over Malhotra et al. in view of Bustard et al.

Claims 3, 4 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over Malhotra et al. in view of Bustard et al. and further in view of Applicants' admitted state of the prior art (see page 3 of the specification as filed).

The disclosure at page 3 of the specification as filed indicates that dextran formed from *Leuconostoc mesenteroides* bacteria is known, and that such dextran typically has a molecular weight of 40,000.

As previously noted there is no disclosure in Malhotra et al. that the recording sheets disclosed therein would be suitable for use in any surgical procedure. The recording sheets are not suggested as being suitable as prosthetic grafts and are non-sterile. Further, one skilled in the art would have no motivation to combine Malhotra et al. (relating to ink jet technology) and Bustard et al. (relating to radioactive waste material). Claims 3 and 4 are therefore novel and inventive over the cited prior art.

As discussed above, one of ordinary skill in the art would not consider using the ink jet technology disclosed in Malhotra et al. in the formation of a prosthetic graft. Neither Malhotra et al. nor Bustard et al. suggest the step of introducing a flexible graft material into a mixture of dextran, formaldehyde and urea and then causing said mixture to polymerize. Furthermore, one skilled in the art would have no motivation to combine Malhotra et al. (relating to ink jet technology) and Bustard et al. (relating to radioactive waste materials). Claim 15 is therefore novel and inventive over Malhotra et al. in view of Bustard et al. and further in view of Applicants' admitted state of the prior art.

Claims 5 to 10 are rejected under 35 U.S.C. 103(a) as being obvious over Bass et al. (US 5,292,362) in view of Lentz et al. (US 5,851,229) and Malhotra et al.

Bass et al. discloses a composition suitable for coating prosthetic materials, and providing a water tight or water resistant seal thereon (see column 4, lines 12 to 21). The composition provides a tissue bond having high tensile strength, elasticity, deformability, water tightness, viscosity and adhesivity (see column 8, lines 3 to 9). The composition comprises a first component, which provides tensile strength to the composition and may also provide a water tight seal to a tissue or prosthetic implant surface (see column 4, lines 29 to 34). The composition also includes a second component adapted to support the first component and provide an improved degree of inter-relationship to the molecules of the first component. The second component of the composition is present merely to support the first component (see column 4, lines 29 to 38), and does not provide any strength to the composition or

allow a water resistant seal to form.

The second component may be, amongst other compounds, a saccharide, preferably a cross-linked saccharide (see column 5, lines 9 to 19). There is no suggestion that cross-linking may occur though formaldehyde and urea condensation, and Bass et al. makes no teaching that the second component may be dextran. The only mention made of dextran in Bass et al. is as a viscosity modifier (see column 6, lines 27 to 36). Bass et al. makes no suggestion that the viscosity modifier may be cross-linked. As noted in Lentz et al. the vascular grafts formed according to Bass et al. are not easily manufactured, and the coatings disclosed in Bass et al. may become denatured and cease to function. In addition, such surface coatings are readily and swiftly biodegradable (see column 3, lines 11 to 29 of Lentz et al. describing US 5,209,776: Bass et al. is a continuation-in-part of US 5,209,776). This is in contrast to the graft of Claims 5 to 9 which is resorbed at an appropriate rate for tissue growth.

Lentz et al. discloses a porous vascular graft and a method of making such (see column 1, lines 5 to 13). The porous vascular graft comprises a substantially blood-tight coating for a vascular graft being a hydrogel formed from a combination of at least two polysaccharides (see column 3, lines 63 to 67) or a polysaccharide and a protein (see column 4, lines 27 to 30). There is no suggestion in Lentz et al. that the hydrogel may comprise dextran. The hydrogel may be cross-linked to form a tighter barrier around the graft (see column 4, lines 61 to 64 and column 6, lines 35 to 65). Lentz et al. make no suggestion that cross-linking may occur through formaldehyde and urea condensation of the hydrogel. The vascular graft is formed by impregnating the

graft with the hydrogel sealant composition (see column 15, lines 9 to 10). The impregnated graft may be dried at room temperature (22 to 25°C), or at a temperature of 60°C (see column 15, lines 1 to 8).

The graft formed according to the method of Lentz et al. is porous (see column 1, lines 5 to 13 of Lentz et al.) in contrast to the substantially non-porous graft formed according to the method of Claims 5 to 9. One of ordinary skill in the art would not consider using a method of forming a porous graft to form a substantially non-porous graft.

The Examiner considers it would have been obvious to one of ordinary skill in the art to use the method of coating grafts disclosed by Lentz et al. to form the vascular graft of Bass et al. However, Lentz et al. notes the disadvantages associated with the coatings disclosed in Bass et al. (see column 3, lines 11 to 27 of Lentz et al.) and upon reading Lentz et al., one skilled in the art would consider the properties of the coating of Bass et al. to be unacceptable and would not consider combining these documents. However, even if these two documents were combined as suggested by the Examiner, the skilled man would not be in possession of the present invention. Neither Bass et al. nor Lentz et al disclose cross-linking dextran. Dextrans are not easily cross-linked as they have limited reactive sites to form intermolecular bonds. The available groups are almost exclusively hydroxyl (OH) groups (see page 3, lines 11 to 14 of the Application as filed). The present invention provides a method of forming cross-linked dextran, and this method is not suggested by either Bass et al. or Lentz et al.

Cross-linking dextran through formaldehyde and urea condensation ensures that a dextran polymer is formed comprising bonds sufficiently labile to permit resorption at an appropriate rate for tissue ingrowth. Furthermore the cross-linked dextran polymer breaks down into simple products, which may be easily disposed of by the body (see page 4, lines 3 to 10 of the specification as filed). Cross-linked dextran bonds may be subject to hydrolytic degradation. The degradation products of cross-linked dextran are likely to comprise sugar units, urea, formaldehyde and small complexes of the latter components (see page 8, lines 6 to 15 of the specification as filed). These are easily disposed of by the body.

The Examiner seeks to remedy the deficiencies present in the combination of Bass et al. and Lentz et al. by referring to Malhotra et al. Malhotra et al. teach that urea-formaldehyde may be used as a cross-linking agent, but neither Bass et al. nor Lentz et al. suggest cross-linking dextran. Furthermore, the Examiner does not explain the motivation to one of ordinary skill in the art in combining a document relating to ink jet technology (Malhotra et al.) with documents relating to prosthetic grafts (Lentz et al. and Bass et al.).

The method of Claims 5 to 9 is therefore novel and inventive over the cited prior art documents.

The Examiner asserts that Lentz et al. inherently teaches grafts formed according to the method disclosed therein, and that Claim 10 therefore lacks inventiveness over Bass et al. in view of Lentz et al. and further in view of Malhotra et al. Claims 1 and 10 have now been combined and Claim 10 has been cancelled. Neither Bass et al. nor Lentz et al.

disclose a graft comprising cross-linked dextran. Malhotra et al. is in a completely different field to both Bass et al. and Lentz et al. and one of ordinary skill in the art would not be motivated to combine these documents. Further, the use of urea-formaldehyde as a cross-linking agent as taught by Malhotra et al. is of little relevance if there is no suggestion to include dextran in cross-linked form in any of the prior art documents. Claim 1 as amended is novel and inventive over the cited prior art documents.

Applicant submits that the Examiner's rejections under 35 USC 102 and 103 have been overcome by the amendment of the claims and that the claims of the present application as amended are novel and inventive over all of the documents cited against them. Issuance of a patent is therefore solicited.

Respectfully submitted,

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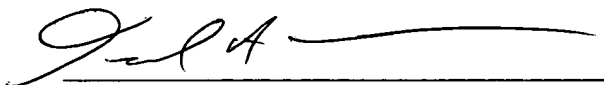

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